**EXHIBIT 4**

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HONORABLE RICARDO S. MARTINEZ

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON

| | |
|---|---|
| UNITED FARM WORKERS[1]; SEA MAR COMMUNITY HEALTH CENTER; PINEROS Y CAMPESINOS UNIDOS DEL NOROESTE; BEYOND PESTICIDES, FRENTE INDIGENA DE ORGANIZACIONES BINACIONALES[2], and ARNULFO LOPEZ,<br><br>Plaintiffs,<br><br>v.<br><br>ADMINISTRATOR, U.S. ENVIRONMENTAL PROTECTION AGENCY,<br><br>Defendant,<br><br>and<br><br>GOWAN COMPANY, MAKHTESHIM AGAN of NORTH AMERICA, INC, and BAYER CROPSCIENCE LP,<br><br>Defendant-Intervenors. | Civ. No. CV04-0099-RSM<br><br>OPPOSITION TO CROSS-MOTIONS FOR SUMMARY JUDGMENT AND REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT AS TO AZINPHOS-METHYL<br><br>NOTED ON MOTION CALENDAR: FRIDAY, OCTOBER 26, 2007<br><br>ORAL ARGUMENT REQUESTED |

[1] Formerly United Farm Workers of America, AFL-CIO.
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## INTRODUCTION

Based on its standard methodologies and agency investigations of grower impacts, defendant Environmental Protection Agency ("EPA") appropriately found that the risks of continued AZM use outweigh any benefits. However, EPA backtracked from these findings and allowed the continued use of azinphos-methyl ("AZM") for six more years based not on objective evidence but rather by acquiescing in the positions advocated by the AZM registrants and growers. In deferring to the desires of the registrants and growers, EPA abdicated its duty to conduct an independent investigation to determine whether demonstrable benefits override the very serious risks of concern that AZM poses to workers and the environment.

## I. EPA AGREES THAT FIFRA PLACES THE BURDEN OF PROOF ON THE REGISTRANT TO DEMONSTRATE THAT BENEFITS OF CONTINUED AZM USE OUTWEIGH ITS HEALTH AND ENVIRONMENTAL RISKS.

In its opposition to plaintiffs' summary judgment motion and its cross-motion, EPA agrees that "the registrant bears the burden of establishing throughout the administrative process that its product's benefits outweigh the risks." EPA Opposition at 4. The parties also agree that EPA has established levels of concern for workers, fish, and wildlife and that it uses standard methodologies to determine whether use of a pesticide exceeds these levels, in which case it poses what EPA calls "risks of concern." EPA Opposition at 1-2. Applying these standard methods, EPA determined that all remaining AZM uses pose risks of concern for pesticide handlers, field workers, fish, and other wildlife. A pesticide use that poses any such risks of concern is ineligible for registration unless the registrants prove and EPA finds that the AZM use has overriding and demonstrable benefits that outweigh the risks. EPA Opposition at 3-4.

Rather than identify demonstrable overriding benefits, EPA claims that Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") gives it essentially unbridled discretion to strike whatever balance it deems appropriate. EPA Opposition at 1-3, 19. However, the case cited by EPA in support of its plea for deference provides as follows:

> [T]he court has an obligation to ensure that the administrator has made a reasoned decision, which conforms to the legislative language and purpose. And close



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> scrutiny of administrative action is particularly appropriate when the interests at stake are not merely economic interests in a license or a rate structure, but personal interests in life and health.

Wellford v. Ruckelshaus, 439 F. 2d 598, 601 (D.C. Cir. 1971).

EPA recognizes that the FIFRA decisions are subject to judicial review under the standard set out in the Administrative Procedure Act ("APA"), under which the Court must set aside agency actions that fail to give appropriate weight to relevant factors, that offer an explanation that runs counter to the evidence before the agency, that cannot be ascribed to agency expertise, or that deviate from the controlling law, here the mandates in FIFRA. EPA Opposition at 14. Under these standards, the six-year extended registration of AZM must be set aside for the following reasons:

1. EPA agreed to the registrants' phase-out package to avoid a contested cancellation proceeding without estimating the amount of time cancellation would take and conducting a risk-benefit analysis to determine whether the risks from AZM use during that period would be outweighed by the benefits of obtaining cancellation sooner than under the six-year package.

2. There is no analysis in the 2001 Interim Reregistration Eligibility Decision ("IRED"), the 2006 AZM decision, or any other final agency document of the feasibility and cost-effectiveness of requiring closed cabs for AZM applications, let alone any risk-benefit balancing to support EPA's failure to require such mitigation.

3. EPA conducted a cursory, incomplete, and often inaccurate investigation to determine the extent to which export markets would be impacted by a shift to AZM alternatives, the most glaring omission being the lack of any objective estimate of how long any large-scale export disruptions would last, and it therefore lacked an adequate basis for believing benefits outweigh risks to workers and the environment.

4. EPA's decision lacks objective evidence supporting a transition period longer than a couple years.

5. EPA acknowledged that serious risks of concern to workers, bystanders, and the environment would persist during the phase-out and lacked objective evidence that the mitigation in the phase-out package would bring about a significant enough reduction to justify allowing such risks.

6. EPA misused spotty incident data to draw inferences from the lack of large numbers of reported incidents when EPA has repeatedly recognized that the



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incident databases suffer from severe underreporting and offer no credible basis for predicting the frequency or magnitude of risks.

7. EPA conducted an inadequate investigation of the cost-effectiveness of organic production as an alternative to AZM based on EPA's unsupported assertion that organic prices will decline.

8. EPA conducted an inadequate risk-benefit analysis by failing to aggregate and account fully for all risks to workers, bystanders, and the environment and failing to require objective evidence that grower economic impacts and other benefits outweigh the demonstrated risks.

In making its AZM phase-out decision on the basis of subjective beliefs regarding AZM's benefits without supporting evidence, EPA has turned FIFRA's burden of proof on its head. It acceded to the registrants' and growers' demands rather than make an independent risk-benefit decision based solely on the demonstrated risks and benefits, and it failed to require objective evidence of overriding benefits before allowing workers and the environment to be subjected to serious risks of concern. Because of these defects, the Court should remand the 2006 AZM decision to EPA for further risk-benefit balancing based on objective data, rather than argument and conjecture, and for a full explanation of how each risk of concern and all such risks combined are outweighed by demonstrable benefits.

## II. EPA LACKED OBJECTIVE PROOF THAT BENEFITS OF CONTINUED AZM USE FOR SIX MORE YEARS OUTWEIGH THE DEMONSTRABLE HARM TO WORKERS, BYSTANDERS, AND THE ENVIRONMENT.

### A. The Record Does Not Justify a Phase-Out as Long as Six Years in Order to Avoid Cancellation Proceedings.

EPA tries to justify the lengthy phase-out because the registrants agreed to it, eliminating the need for EPA to pursue cancellation administratively. In defending this justification, EPA accuses United Farm Workers ("UFW") of arguing that the time it would take to obtain cancellation is not a valid consideration. EPA Opposition at 33. To the contrary, in its motion (at 27-28 n.16), UFW recognized that the registrants' voluntary cancellation can be considered, but only where the record demonstrates that earlier cancellation due to the registrant's voluntary agreement will result in a substantial reduction of risk that outweighs the remaining risks.



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*1. EPA must but failed to estimate how long the time cancellation proceeding would take.*

In National Coalition Against the Misuse of Pesticides v. EPA, 867 F.2d 636 (D.C. Cir. 1989) ("NCAMP"), EPA had determined that the registrant's voluntary cancellation, which allowed existing stocks to be used, would result in less of the pesticide being produced and used than would occur during the time it would take EPA to obtain a cancellation. Indeed, the voluntary agreement would result in an estimated two months supply of the pesticide being used, id. at 639, while a suspension proceeding would likely take six months, and a cancellation proceeding some additional time, during which greater quantities of the pesticide would be produced and distributed in commerce. Id. at 640. The court of appeals upheld this finding because the settlement provides for less pesticide use than would occur as a result of formal cancellation proceedings. Id. at 641 (deeming continued sale of pesticide during cancellation proceeding to be the most important factor).

In contrast to the EPA finding in NCAMP, here EPA offered no estimate of the length of time an AZM cancellation proceeding would take. In Love v. Thomas, 858 F.2d 1347, 1350 (9th Cir. 1988), the Ninth Circuit observed that "cancellation or reclassification proceedings take one or two years to complete." In that case, the EPA Administrator issued an emergency suspension order upon finding that the risks associated with continued dinoseb use during the period necessary to complete a cancellation hearing would outweigh the benefits: "For purposes of this determination and in conformity with the timetable for any cancellation hearing held pursuant to the Notice of Intent to Cancel for dinoseb products issued today, I have assumed that a cancellation hearing concerning the various registered dinoseb products would require approximately 18 months." 51 Fed. Reg. 36,634, 36,635 (1986); Love, 858 F.2d at 1350 n.2 (relying on EPA Administrator estimate); see also S. Rep. 92-970, 92d Cong., 2d Sess., reprinted in 1972 USCCAN at 4094 (in enacting FIFRA's cancellation procedures, Congress sought to accelerate the cancellation process and lamented the fact that cancellation proceedings had been taking 13 months, 15 months, and as long as 2 and ½ years).



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EPA acquiesced in the registrants' longer phase-out package and reduced mitigation for the five AZM uses at issue to avoid contested cancellation proceedings, but it never estimated the amount of time cancellation proceedings would take, let alone the amount of pesticide use and risk that would occur during that time frame compared to under the phase-out package. In the absence of such an estimate and analysis, EPA could not and did not base its phase-out decision on an objective balancing of risks and benefits and on evidence in the record. The sole reference that EPA makes to the length of cancellation proceedings is its assertion in its opposition (at 34) that the registrants' voluntary agreement justified extending the phase-out from four to six years. However, EPA must have a valid objective basis for finding that risks would be reduced due to any voluntary agreement to the point where they are outweighed by benefits, whether it is the three-year phase-out of the nut crops, the four-year proposal, or the six-year phase-out. In other words, the appropriate time frame for comparison is the 18 months or less that it would take for contested cancellation proceedings and whatever timeline is embodied in the voluntary agreement. See Dow Chemical Co. v. Blum, 469 F. Supp. 892, 898 (E.D. Mich. 1979) (risk-benefit balancing for emergency suspension order focused on the 3 and 1/2 months the challenged emergency suspension order would be in effect and court found benefits would be nominal during such a short period of time).

*2. EPA must but failed to assess whether the risk reduction that would occur during the voluntary cancellation period outweighs remaining risks.*

By agreeing to the registrant and growers' demands in order to avoid contested cancellation proceedings, EPA gave the registrants enormous power over the terms of the phase-out decision. More specifically, two registrants indicated that they would work with EPA only if EPA would back away from the 2006 proposal and made a veiled threat that they were otherwise "not prepared to accede to any arrangements which foreclose their existing legal rights to obtain review of EPA registration cancellation." AR 1386 at 2.[3] EPA took what might have been a bluff at face value and

[3] UFW is citing to administrative record documents as "AR" followed by the document number. Along with this brief, UFW is submitting the AR documents that it has cited, which have not been filed by EPA with the Court.



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agreed to the registrants' demands, even though a registrant may advocate strenuously against cancellation only to agree to a cancellation once a notice of intent to cancel is issued. In essence, EPA abdicated its statutory responsibilities and rubber stamped the position advocated by the registrants. See West Harlem Environmental Action, 380 F. Supp. 2d 289, 296 (S.D.N.Y. 2005) (EPA cannot reflexively rubber stamp the regulated industry's position but must instead independently perform its decisionmaking functions).

Not only did EPA extend the time frame for the phase-out, but it also agreed to numerous other demands made by the registrants. The most significant such demand is that the six-year phase-out might not really be a phase-out at all. EPA has agreed to conduct another risk-benefit decision for AZM if certain conditions are met and to make a new registration decision for AZM before the six years expire. AR 1679 at 3.[4] For each of the AZM uses at issue, EPA promised to amend the cancellation order to allow use after the six-year phase-out if it believes there is a need for AZM after that time. AR 1459 at 14, 17, 20, 24, 25. In other words, the 2006 AZM decision is similar to the 2001 time-limited registration in that the registrants can seek and EPA will consider allowing continued registration of the five AZM uses well beyond 2012. In addition, in the final decision, EPA agreed to the registrants' demands by eliminating the previously proposed medical monitoring of post-application workers, which might have provided a more accurate record of impacts for the 2012 risk-benefit decisions than the type of haphazard incident reporting used by EPA in the 2006 decision. EPA also shrunk the buffers around streams, as well as the buffers around homes, schools, and day cares, even though it found that children and other bystanders

[4] Under the agreement, EPA must make a new registration decision unless (1) there are alternative pest control practices that provide approximately the same control under high pest pressure based on a two-year evaluation under commercial conditions by land grant university scientists in each production region that rates the practice good to excellent; and (2) there are maximum residue level regulations for such pesticides that allow export of the crop to all significant export markets. AR 1679 at 3. This agreement locks in the registrants' view that MRLs must be established in all key export markets, even though EPA has not embraced that position, see EPA Opposition at 30, and it calls for a type of commercial assessment and efficacy standard for pesticide alternatives that EPA has never required and that deviates from FIFRA's risk-benefit test.



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would be exposed to serious risks of concern under the reduced buffers. AR 1456.

In the 2006 AZM decision, EPA contends that it obtained mitigation, including rate reductions, buffer zones, and the early phase-out of certain uses, more quickly by agreeing to the extended six-year phase-out package. AR 1459 at 14. However, this assertion is not borne out by the record. First, EPA concedes that the amount of AZM that will be used during the life of the phase-out will be 15% more than under the proposed decision. Id. Moreover, while EPA's decision calls for reductions in application rates for the remaining AZM uses, the usage rates will not be decreased to levels below typical application rates until 2010 or later for the various crops. For example, the typical pre-phase-out application rate for apples was 0.78 lbs. per acre per application with three applications per season (or 2.34 lbs. per season), and EPA's rate reductions will not force reductions below this level until in 2010. While there is an intermediate cap of 3 lbs. per season in 2008-2009, the apple industry had proposed this cap in its negotiations with EPA, which EPA had incorporated into its June 2006 proposal. AR 1459 at 10, 15; AR 1444 at 2; AR 1355 at 11. Similarly, for cherries and highbush blueberries, the phase-out caps will not force reductions below typical usage patterns until 2010; for pears, reductions would not begin until 2011; and for lowbush blueberries, no reductions will be required since current typical application rates are well below the caps even for 2012. AR 1459 at 17, 18, 20, 21, 24; AR 1249 at 2; AR 1251 at 3.[5] Any cancellation proceeding would long be concluded by the time EPA's application rate reductions would result in any significant decline in AZM usage on these crops.

Second, the AZM phase-out increased buffer zones around water bodies from 25 to 60 feet and established 60-foot buffer zones around homes, schools, and other occupied dwellings. AR

[5] The 2006 AZM decision erroneously lists typical pear application rates that would exceed the maximum allowed under the label, but the grower impact assessment reports lower, legal usage patterns for pears. Cf. AR 1459 at 15 with AR 1249 at 2. The proposal also lists lower typical application rates for highbush blueberries, which would render the 2010-2012 cap essentially meaningless. AR 1355 at 14 (0.39 lbs./application up to 2 applications/year); AR 1459 at 20 (0.75 lbs./year cap). In addition, the proposal would have immediately capped application rates at 1 lb./year for blueberries, while the final decision does not reduce applications below 1.25 lbs/year until 2010. Cf. AR 1355 at 17 with AR 1459 at 20.



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1459 at 15, 18, 20-21, 24, 26; cf. AR 1459 at 28-31 (buffer zones around water bodies range from 300-500 feet for the nut crops). However, these buffers will not become effective until the 2008 growing season, by which time the cancellation proceeding would be completed or nearly so. 72 Fed. Reg. 44,511 (Aug. 8, 2007) (soliciting public comment before approving registration and labeling changes conforming to AZM decision). Moreover, the final package to which the registrants agreed shrunk the buffers around water bodies from 100 feet to 60 feet, acceding to industry demands. Cf. AR 1355 at 11, 14, 17, 20; see AR 1444 at 2. In Washington, Oregon, and California, this Court had already ordered EPA to require 60-foot buffers for AZM ground and airblast applications along salmon and steelhead streams. Washington Toxics Coalition v. EPA, No. C01-0132C (Jan. 22, 2004), aff'd, 413 F.3d 1024 (9th Cir. 2005), cert. denied, 546 U.S. 1090 (2006).[6]

Third, EPA points to the early phase-out of certain uses, but neither the registrants nor the growers contested the immediate 2007 phase-out of two uses, and the final decision postponed the phase-out of the nut crop uses for two years. EPA points to nothing in the record suggesting that cancellation of those uses would have precipitated contested cancellation proceedings.

Under FIFRA, EPA cannot simply accede to the registrants' and growers' demands because it wants to make a deal to avoid contentious litigation. Instead, it must have an objective basis for determining whether the deal will reduce risks to a greater extent than pursuing cancellation. See, e.g., Love, 858 F.2d at 1358-62; West Harlem Environmental Action, 380 F. Supp. 2d at 294-96. EPA must estimate how long the cancellation proceeding would take and assess the risk reduction that would be accomplished by the voluntary agreement during that period of time. EPA failed to undertake this essential inquiry before acceding to the industry's phase-out package.

[6] While the AZM phase-out calls for vegetated buffers, it does not prescribe specific standards for such vegetation to ensure maximum effectiveness in diverting and absorbing pesticides, as experts and government agencies have deemed necessary. See Decl. of David Zaber ¶ 15 (Nov. 26, 2002), in Washington Toxics Coalition (cited by registrants at 22); http://www.nrcs.usda.gov/technical/Standards/nhcp.html. Moreover, the record does not address how long it will take to grow sufficient vegetation to ensure the buffers will perform such functions.



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B. EPA Offered No Explanation or Risk-Benefit Analysis to Justify the Continued Use of AZM Without Closed Cabs to Reduce Serious Poisoning Risks to Workers.

Workers applying pesticides in open cabs face extremely serious risks of poisonings. The Margins of Exposure ("MOE") range from 14 to 18, far lower than EPA's threshold for risks of concern (an MOE less than 100 poses a risk of concern). EPA identified mitigation in the form of closed cabs that could increase the MOEs substantially, although risks of concern would still exist for apples, pears and blueberries. AR 1459 at 10, 15, 18, 21. Inexplicably, EPA did not require closed cabs for air blast applications, and remarkably, it offered no explanation for this failure in either the 2001 IRED or the 2006 AZM decision.

Under FIFRA's risk-benefit test, EPA cannot register a pesticide use that causes risks of concern without demonstrating that benefits outweigh those risks. It has long been recognized that "[o]nce the Administrator has found that a risk inheres in the use of a pesticide, he has an obligation to explain how the benefits of continued use outweigh that risk." EDF v. EPA, 548 F.2d 998, 1012 (D.C. Cir. 1976). EPA "bears the burden of justifying its lack of action" to protect the public from a pesticide in the face of evidence of serious health hazards. EDF v. EPA, 510 F.2d 1292, 1302 (D.C. Cir. 1975).

Contrary to this mandate, EPA's AZM decisions are utterly silent as to closed cab mitigation. Nor did EPA justify its failure to require closed cabs in its proposals or its responses to public comments. The appropriate remedy is for the Court to remand the issue of closed cab mitigation for pesticide handler risks and direct EPA to conduct risk-benefit balancing to determine whether the risks are justified by overriding benefits.

EPA contends that its failure to address closed cabs is not a fatal omission and that it may supply the missing explanation in its pleadings before this Court. EPA Opposition at 25 ("EPA may reasonably explain its decision to a reviewing court."). In support of this novel twist on administrative law, EPA quotes from an out-of-circuit district court decision. Id., quoting National Oilseed Processors Ass'n v. Browner, 924 F. Supp. 1193, 1204 (D.D.C. 1996), aff'd in part on other grounds, 120 F.3d 277 (D.C. Cir. 1997). That case allows an agency to provide "further" or "a



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clearer or more detailed explanation," not to offer an explanation where the record contains none. The case distinguishes "between a post hoc rationalization, which is a new rationale for an agency action, and a post hoc explanation, which is an agency's discussion of the previously-articulated rationale for the challenged action. Post hoc rationalizations are precluded; post hoc explanations are not." 924 F. Supp. at 1204.

Ignoring this distinction, EPA's lawyers have constructed a new justification for not requiring closed cabs, which EPA made public for the first time in its summary judgment pleading. In that justification, EPA agrees that Pesticide Registration Notice 2000-9, at 8, instructs EPA to reduce worker risks to the greatest extent feasible with protective equipment and engineering controls, and that closed cabs constitute such an engineering control. EPA Opposition at 26. Accordingly, EPA recognizes that it must determine whether closed cabs constitute feasible mitigation. Id.[7] While EPA claims that it relied on two sources to find that closed cabs may not be feasible in certain circumstances, neither source supplies a reasoned agency analysis for its determination.

First, EPA points to the positions taken by trade groups representing various growers who were advocating for continued AZM usage for their crops. On the one hand, EPA cites emails from three nut trade groups indicating that almond growers "can work with the requirement of enclosed cabs for applicators," AR 1914, the pistachio growers "did not have a problem with the closed cab application," AR 1915, and the walnut growers "are willing to work with" this condition, AR 1916. EPA cites these three emails as the sole support for its determination "that it was a feasible and cost-effective measure" to require closed cabs for the nut crops. EPA Opposition at 24. The apple growers, on the other hand, had a problem with closed cabs and told EPA they would not accede to a mitigation and phase-out package that required closed cabs. AR 1450 at 2 (Apple Industry letter

[7] The registrants contend (at 16) that requiring any particular form of mitigation is optional under the PR Notice as long as risks are reduced to acceptable levels. Here, however, the risks to pesticide handlers in open cabs remain of concern even with the mitigation that has been required, making more mitigation necessary to eliminate the risks of concern.



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to EPA); Registrant Opposition at 16 n.12.[8] By citing these industry positions, EPA suggests that it can treat the willingness of grower advocacy groups to accept certain mitigation as a surrogate for an EPA feasibility determination. To the contrary, as Dr. Frank Ackerman explains, agencies assess the feasibility of regulatory options by determining objectively what is capable of being done, not by asking the regulated industry what it is willing to do. Second Declaration of Dr. Frank Ackerman ¶¶ 3-4, 8 (Oct. 2, 2007); see infra at 26 n.19. Indeed, if the regulated industry's preferences dictated feasibility, many public health regulations, such as the removal of lead from gasoline or requiring seat belts and air bags in automobiles never would have happened. Id. ¶ 5, 8. Accordingly, to allow worker risks of concern to continue, EPA must make objective feasibility and benefits determinations, rather than accede to the advocacy positions of particular grower organizations. See West Harlem Environmental Action v. EPA, 380 F. Supp. 2d at 294-96 (EPA registration decision overturned because EPA uncritically accepted a report without performing an independent analysis of the underlying evidence).

Second, EPA cites a 1999 draft document hastily added to the third version of the administrative record for the 2006 AZM decision when EPA filed its summary judgment motion and opposition. This document lacks authenticating information identifying who prepared it, how and whether it was transmitted to decisionmakers, and even its date. AR 1917. EPA never cited this draft in its occupational risk assessments, its 2001 IRED, its benefits and grower impact assessments, its proposed 2006 AZM decision, or its final 2006 AZM decision. While EPA made its benefits assessments, grower impact assessments, and proposed 2006 decision available for public comment, this "assessment of the costs of switching to enclosed cabs" never saw the light of day until it proved useful in this litigation.

Interestingly, it is plaintiffs that have urged EPA to include in the administrative record drafts and internal agency exchanges, even if they are not incorporated into the final decisions. See

[8] In a footnote (at 26 n.20), EPA's opposition cites an orchard survey conducted by the American Farm Bureau that EPA never referenced in its AZM decisions. See AR 1824.1 at 7, 15. A survey conducted by a trade group does not supply a reasoned and objective EPA analysis of feasibility.



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Letter to Christina Parascandola (April 8, 2005) (Exhibit 1). EPA steadfastly opposed including drafts in the administrative record on the theory that they do not embody the agency's decision. See Letter from EPA (July 1, 2005) (Exhibit 2). EPA is now making a selective exception to this principle in order to fill a void in the record and to draw from this draft in crafting a post hoc rationalization for failing to require closed cabs.

Even apart from the propriety of selectively adding this but not other drafts to the administrative record, the document itself contains an extremely outdated analysis. It pertains to all crops assessed in the 2001 IRED, even though AZM is no longer registered for several dozen of those crops. It encompasses the nut crops, even though the nut growers have since told EPA that they are willing to use closed cabs, undercutting the draft's contrary assertion that closed cabs would be too expensive for nut crops. It is also entirely unclear whether the cost estimates remain valid with the passage of time. More growers may have access to closed cabs or the cost may have decreased. In addition, closed cabs are now required for other pesticides that similarly pose excessive poisoning risks to pesticide applicators, which would make closed cabs the cost of doing business rather than a cost of using only one neurotoxic pesticide. See, e.g., 2002 IRED for Disulfoton at 75; 2002 IRED for Ethoprop at 85-86; 2002 IRED for Methamidiphos at 52 (available at http://www.epa.gov/pesticides/reregistration/status.htm). If EPA had wanted to rely on the draft assessment in its 2006 AZM decision, it would have had to update the analysis, like it did with its other benefits analyses.

Apart from relying on the resurrected draft assessment, EPA's opposition tries to minimize the worker risks of concern, but does so by creating a post hoc rationalization that cannot be found in the challenged decisions. For example, EPA claims that the risks of concern may have been reduced because the 2001 IRED required additional protective clothing for pesticide applicators. EPA Opposition at 25. However, EPA's 2006 worker risk assessment quantifies worker risks with and without closed cabs and reveals serious risks of concern to handlers in open cabs for apples, pears, cherries, and blueberries. AR 1357 at 20-22. Indeed, EPA expressly found that the mitigation required to date would not reduce those risks to acceptable levels and that pesticide



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handlers will continue to face risks of concern even with all the required mitigation. See AR 1459 at 6, 10, 15, 18, 21. In the face of such risks of concern, EPA had to go on to determine whether any overriding benefits justify subjecting workers to these poisoning risks.

C. EPA's Investigation of Export Impacts Was Too Incomplete and Inaccurate to Provide an Objective Basis for Finding That Trade Disruption Impacts Override the Risks to Workers and the Environment Over the Next Six Years.

EPA allowed at least six more years of AZM use, in large part, because there may be some amount of disruption in "a portion" of the export markets for four of the five remaining AZM uses. EPA Opposition at 30. EPA's analysis of potential export impacts, however, is fatally flawed. First, EPA failed to provide an objective and documented basis for the length of time any such disruptions would be likely to occur. Second, EPA conducted an inadequate and incomplete investigation of the status of maximum residue levels ("MRLs") for the AZM alternatives, and without such an investigation EPA lacked a sufficient basis to assess the extent of any export impacts. See Love, 858 F.2d at 1358-62 (EPA's suspension of pesticide uses was arbitrary and capricious because EPA failed to conduct adequate investigation of grower impacts). Related, EPA deemed any potential trade disruption to "a portion" of the export market to outweigh the worker and environmental risks, without regard to the magnitude of that impact. These flaws render EPA's reliance on export impacts arbitrary, capricious, unsupported by the record, and contrary to FIFRA's risk-benefit balancing standard.

*1. EPA had no basis for believing that large-scale export disruptions would occur for the next six years.*

In the proposed AZM decision, EPA stated, without citation, that MRLs would likely be in place for the key AZM alternatives for four crops by 2010. AR 1355 at 11, 14, 16, 20. The final AZM decision makes the same unsupported assertion, except that it substitutes 2012 for 2010. EPA made these statements generically for all four crops without regard to the number of AZM alternatives lacking MRLs for the particular crop in key export markets. EPA also ignored any progress being made in key export countries to adopt pertinent MRLs, even though the only investigation in the record states that "MRLs change over time at different paces in different



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countries" and that many MRLs are under development." AR 1363 at 2, 8.

In order to determine whether the benefits of AZM use over the next six years would outweigh the demonstrated risks to workers and the environment, EPA had to know how long any export markets would be unavailable to each particular crop. By way of analogy, before EPA can agree to a voluntary cancellation, it must find that the benefits of the immediate cancellation outweigh the risks, see NCAMP, 867 F.2d at 639-40, and a critical component of that inquiry is the length of time the cancellation would take. See supra at 3-5. Similarly, EPA cannot assess the magnitude of any export disruptions without first determining how long it will take for MRLs to be in place in the key export markets.

In the final AZM decision, EPA makes the conclusory assertion that growers can shift to alternatives for which MRLs are in place within six years. AR 1459 at 14. However, it cites no analysis or data to support this assertion. The "initial" examination conducted before the AZM proposal remains the only EPA analysis in the record, and it offers no estimation of how long it will take for MRLs to be adopted. At the same time, the initial examination recognizes that the MRL picture will likely change quickly as most export market countries have MRLs for at least one of the AZM alternatives, many other are under development, and many countries use Codex or other MRLs, rather than develop their own standards. AR 1363 at 1, 8.

In its brief, EPA contends that it cannot predict precisely how long it will take for MRLs to be established and therefore six years is a reasonable estimate. EPA Opposition at 31. EPA provides only one citation to support the reasonableness of its six-year projection and this is a citation to a comment submitted by the apple industry, asserting that it can take up to eight years for approval of new Codex MRLs. EPA Opposition at 30-31. The apple industry comment makes this assertion without any citation and without reference to any of the AZM alternatives at issue. AR 1452 at 13. Not only does the apply industry claim lack support, but it is inappropriate for EPA to rely on the apple industry comment in its legal brief when it never credited this assertion in its deciding to allow AZM use to continue for six more years. See West Harlem Environmental Action, 380 F. Supp. 2d at 294-96 (EPA has an obligation to investigate the evidence underlying



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reports and arguments presented to avoid FIFRA registration decisions restricting pesticide use).

Nor would it have been appropriate for EPA to accept an unsubstantiated allegation by the apple industry about the length of time it takes to establish a Codex MRL. EPA is no bystander to the Codex process. Rather, EPA is one of the three U.S. agencies that manage and carry out U.S. Codex activities, and EPA has long been the United States' lead delegate to the Codex committee that establishes pesticide MRLs. See 72 Fed. Reg. 30,743, 30,743-44 (June 4, 2007); 61 Fed. Reg. 4954 (Feb. 9, 1996); 59 Fed. Reg. 45,662 (1994). Accordingly, EPA is in a position to ascertain precisely where in the MRL-setting process each AZM alternative stands and how long it is likely to take for an MRL to be adopted. EPA is similarly a participant in the North American Free Trade Agreement Technical Working Group on Pesticides, which seeks to harmonize pesticide standards in the three NAFTA countries – the United States, Canada, and Mexico. Indeed, the Director of EPA's Office of Pesticides Programs participated in a recent meeting where this NAFTA pesticide group "approved a proposal to develop and implement a coordinated NAFTA strategy on the phase-out of azinphos-methyl (AZM), including the effective transition to lower risk pest management tools." NAFTA Technical Working Group on Pesticides, Meeting Summary (May 17-18, 2007), available at http://www.pmra-arla.gc.ca/english/pdf/nafta/TWGmay07-mtgsumm-e.pdf.[9] EPA is well-positioned to ascertain how long it will realistically take for countries and international standard-setting bodies to adopt MRLs for AZM alternatives in the top export markets. EPA cannot simply pull a number out of a hat or out of the apple industry comments and claim deference to its judgment when it failed to undertake a reasonable inquiry or to tap its internal expertise.

[9] UFW is citing both the Federal Register notices and the NAFTA pesticides working group summary as extra-record evidence relevant to whether the agency conducted a sufficient investigation in a highly technical area. See Love, 858 F.2d at 1356. As in Love, such extra-record evidence is admissible to assist the Court in determining whether EPA conducted an adequate investigation and whether it considered the relevant factors and relevant and available evidence. Id. at 1356-60; see also West Harlem Environmental Action, 380 F. Supp. 2d at 295 n.2 (court considered extra-record evidence showing that EPA ignored available data relevant to a key issue in the FIFRA registration decision).



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*2. EPA failed to conduct an adequate investigation of the status of MRLs in key export markets.*

EPA conducted only an "initial examination" of MRLs for four crops based on a few information sources. AR 1363 at 1-2. In public comments on the AZM proposal, a prominent economic professor identified numerous flaws. Dr. Frank Ackerman revealed through a minimal Internet search that the process of developing MRLs for these crops was far further along than indicated by EPA. AR 1415 at 6. He faulted EPA for failing "to adequately research the rapidly growing international analysis and regulation of the alternative pesticides." AR 1415 at 7. One might have expected EPA to conduct a more thorough investigation of MRLs in light of the errors uncovered by Dr. Ackerman, but EPA did not. Nor does EPA explain why it based its AZM decision on an "initial examination" that had proven to be marred by errors.

In its brief, EPA concedes that the final AZM decision is "inaccurate" in its presentation of MRLs for AZM alternatives. EPA Opposition at 31 n.24. Nonetheless, EPA asserts that it reasonably relied on the initial examination because the inaccuracies did not permeate the entire examination, MRLs are not currently in place for all AZM alternatives, and, in some instances, phosmet may be the only alternative for a particular export market in the short-term. None of these assertions makes EPA's reliance on a demonstrably inaccurate initial MRL examination reasonable.

First, EPA contends that it could base its decision on an inaccurate examination of MRLs because UFW has demonstrated only a discrete number of errors. Of course, it is EPA, and not UFW, that has the legal duty to conduct a complete and accurate investigation of the impacts of cancelling AZM uses. See Love, 858 F.2d at 1358-62. Neither Dr. Ackerman nor UFW's motion purported to undertake a comprehensive ground-truthing of EPA's MRL representations. Nonetheless, by checking the sources cited by EPA in its initial examination, both uncovered numerous errors. The significance of each such error depends, not on the total number of MRLs affected, but rather on the portion of the impacted export market. For example, Canada, the second largest importer of U.S. apples, has proposed or final MRLs for all AZM alternatives, yet EPA



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treated that market as a complete loss based on erroneous information.[10] Likewise, many export markets would be open to the U.S. exports because the countries use Codex, European Union, or U.S. MRLs as a default, yet the initial examination failed to disclose which markets would remain open on this basis. AR 1363 at 1, 8; see UFW Motion at 18-19 (providing examples of export countries that use Codex or EU standards that allow residues of AZM alternatives).[11]

Second, EPA's initial MRL examination purported to estimate "theoretical worst case loss scenarios," even though it recognized that such an exercise is "speculative" and that "it is highly unlikely that the entire export market value for these crops . . . would be lost if AZM alternatives are used." AR 1363 at 7, 8. EPA recited the "worst case" losses in its final AZM decision, but in its brief, it contends that the "worst case" projection "was not intended to serve as EPA's estimate of the likely revenue losses on crop exports that domestic growers would face in the absence of AZM." EPA Opposition at 30. Instead, EPA asserts that the worst-case projections show that "some portion" or "a portion" of the export market could be at risk in the short-term. Id. By calculating inaccurate worst-case losses and then disavowing reliance on them, EPA has acted inconsistently and arbitrarily. EPA compounds this inconsistency by reciting in its brief a statement made by the

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[10] EPA represented in the final AZM decision that Canada has MRLs for novaluron on apples, AR 1459 at 12, yet it now asserts that the Court should disregard evidence that Canada has such an MRL because it was officially adopted after the 2006 AZM decision. EPA Opposition Brief at 29 n.21. Since EPA was in a position to know that adoption of the proposed novaluron MRL was imminent, the representation in the final AZM decision may have reflected that inside knowledge. In any event, the fact that Canada adopted the novaluron MRL so quickly directly undercuts EPA's assertion that it was reasonable for it to believe it might take six years for such MRLs to emerge.

[11] In its final AZM decision, EPA represented that Codex has an MRL for esfenvalerate on blueberries (but expressed as fenvalerate in the Codex database) AR 1459 at 20, yet in its legal brief, it erroneously asserts to the contrary (at 31 n.24). See http://www.codexalimentarius.net/mrls/pestdes/jsp/pest_q-e.jsp (fenvalerate on berries and small fruit). EPA also claims that it "has been unable to find any confirmation" that Codex is developing an MRL for thiacloprid, but a document on the Codex website indicates that thiacloprid would be evaluated in 2006. Codex Alimentarius Comm'n, Report of the Thirty-Eighth Session of the Codex Committee on Pesticide Residues at 13, 80 available at www.codexalimentarius.net/download/report/655/al29_24e.pdf ("It was pointed out by the JMPR Secretariat that thiacloprid was scheduled for residue evaluation in 2006 and that JMPR would consider all data submitted in a timely manner at that meeting.")



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apple industry in a comment letter. Specifically, EPA reiterates the apple trade group's position that MRLs for all AZM alternatives must be in place in all possible export markets. EPA Opposition at 31, citing AR 1452 at 12. However, EPA did not adopt this position in its decision, and its initial examination took a contrary approach by considering only the top five export markets for each crop, rather than all export markets. AR 1363.[12]

Third, EPA suggests that phosmet would be too costly if it were the only AZM alternative. In making this argument, EPA cites only the loss figures for apples, and indeed, this argument would be inapplicable to other crops, such as pears, where EPA estimated that the additional costs of using phosmet would be minimal. AR 1249 at 4-8 (less than 1% of national pear production). Even as to apples, however, phosmet would be the sole alternative only until MRLs were adopted for the key export markets. Since the two largest export markets have proposed or final MRLs for all AZM alternatives, the phosmet-only cost figures for the life of the phase-out cited by EPA are inapposite.[13]

To base its extension of AZM uses on trade impacts, EPA had to ascertain the extent to which the key export markets would be unavailable and for how long in order to have an accurate picture of the benefits of allowing AZM use during the phase-out period. As EPA recognized in conducting its grower impact assessments, this inquiry must be undertaken on a crop-specific basis. The export markets vary in size for each of the five crops, and the process of adopting MRLs for each AZM alternative is on a different trajectory. Indeed, exports are not a factor at all in the parsley decision, and the impacts are considerably less for cherries and blueberries than for apples. AR 1459 at 20, 23, 25. Yet EPA made a one-size-fits-all determination that a six-year phase-out is

[12] The registrants have submitted a declaration elaborating on their perspective, but this declaration should not be considered because it offers a post hoc rationalization for EPA's phase-out decision, as explained in UFW's opposition to the registrants' motion to supplement the record.

[13] UFW challenges EPA's registration of phosmet for 15 years or more without considering the risks and benefits after AZM has been cancelled and other alternatives in full use. Third Amended Complaint Claim 2.



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warranted for each of these crops to avoid large-scale disruptions in export markets. This assertion runs counter to the evidence in the record and to EPA's responsibility under FIFRA to allow risks of concern only when they are outweighed by demonstrable benefits.

D. EPA Lacked Evidence to Support the Need for Six-Year Transition to AZM Alternatives.

EPA asserts that it became convinced by grower and registrant comments that six years should be sufficient for growers to transition to AZM alternatives. AR 1459 at 14. In its summary judgment motion, UFW faulted EPA for relying on a subjective and impressionistic sense, without supporting citations, for this belief. In its opposition, EPA cites two sources as support for the need for transition time. The first speaks only to tart cherries and indicates that it "will require at least two years to facilitate this transition" with additional training resources. AR 1292 at 2; see also id. at 3. EPA has offered no explanation for adopting a phase-out period that is three times as long as this two-year transition. The second source addresses only apples and explains that there will be an adaptive period of unspecified length to figure out the timing for application of one of the AZM alternatives. AR 1436 at 3; see also AR 1452 at 6 (apple industry trade group comment states that it will take time to learn to work with the new pesticides). Neither of these sources provided support for a transition period as long as six years, nor did they address all of the AZM uses at issue. EPA must have objective evidence to find that benefits will outweigh the risks of support allowing workers and the environment to be exposed to risks of concern for six more years.

E. EPA Lacked Evidence to Justify the Six-Year Extension Based on the Required Mitigation.

EPA admits that the mitigation required during the phase-out will not eliminate risks of concern to workers or the environment. EPA Opposition at 19. Indeed, EPA did not require closed cabs or buffer zones that would have obtained far greater reductions in worker and environmental risks. UFW Motion at 26. And EPA shrunk the buffers from the proposal. Id. at 26-27. Where, as here, EPA finds that a pesticide poses risks of concerns to workers or the environment, it cannot allow that use unless benefits outweigh those risks, and EPA bears the burden of justifying the



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continued use based on demonstrable evidence. EDF v. EPA, 548 F.2d at 1012; EDF v. EPA, 510 F.2d at 1302; Love, 858 F.2d at 1358-62; see Second Ackerman Decl. ¶¶ 9-10 (explaining that transition costs that may be a factor with capital-intensive investments in technology have not been shown here). EPA fell short here.

F. EPA Misused Monitoring and Incident Data.

EPA found that AZM poses risks of concern to workers and to fish and wildlife using its standard risk assessment methodologies. As EPA acknowledges, these findings made AZM ineligible for registration unless benefits are so substantial that they outweigh the risks.

In balancing risks and benefits, however, EPA tries to downplay the magnitude of the risks by pointing to a negative – the absence of an overwhelming number of worker poisonings in the admittedly spotty incident reports that exist. EPA claims that it reviewed these incident reports as part of its "weight-of-the-evidence" assessment of AZM's worker risks. EPA Opposition at 19. This use of incident reports runs counter to EPA's risk assessment methodologies. In its opposition (at 10-12), EPA describes its process for assessing worker risks from cholinesterase-inhibiting pesticides, like AZM, as set forth in agency policy – EPA, Office of Pesticide Programs, The Use of Data on Cholinesterase Inhibition for Risk Assessments of Organophosphates and Carbamate Pesticides (Aug. 18, 2000) ("Organophosphate Risk Assessment Policy") (available at http://www.epa.gov/pesticides/trac/science/#endpoint.) (Exhibit 3).[14] EPA's policy provides for a "weight-of-the-evidence" assessment of available data to determine the levels at which adverse effects may occur. Nowhere does it mention, let alone provide for, the use of incident reports to determine the no-effect or low-effect exposure levels. Instead, the policy requires that the scientific data used in a weight-of-the-evidence analysis be "derived from rigorous experiments with standardized methods and proper controls." Organophosphate Risk Assessment Policy at 16. EPA

[14] EPA cited this document in its opposition. UFW is submitting it as extra-record evidence that describes EPA's standard and highly technical risk assessment process for organophosphate pesticides and to show that EPA has deviated from this policy in its consideration of incident reports in making the 2006 AZM decision.



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is deviating from its standard methodology by considering a lack of numerous poisonings in incident reports to minimize risks of concern from AZM that have been documented through its risk assessment based on credible data.

EPA's reliance on incident reports also runs counter to its findings in the record that it lacks sufficient data to quantify the number of adverse incidents to workers, fish, or wildlife that would be expected to occur based on the calculated risk levels of concern for the various AZM uses. EPA Opposition at 11-12 (risks of concern do not provide reasonable basis for quantifying adverse effects to workers); id. at 12-13 (cannot quantify the potential for or numbers of adverse effects to fish and wildlife). In responding to comments, EPA insisted that its risk assessments do not "provide a basis for making predictions about how many people or non-target organisms will suffer adverse effects from exposure to the pesticide" and that it is "not aware of any scientifically sound methodology that would allow it to do so in this instance." AR 1362 at 5. In its opposition, EPA has stressed that "available incident and monitoring data do not capture the full extent of likely adverse effects occurring in nature" and therefore they cannot be used to "predict, quantitatively, the numbers" of people or workers who will be harmed. EPA Opposition at 13.

EPA is correct in deeming monitoring and incident databases to be of doubtful utility for EPA's risk-benefit balancing. First, EPA does not mandate medical monitoring of workers, poisoning incident reports, or comprehensive water contamination monitoring. As a result, none of these data sources provides comprehensive exposure or incident data. Second, numerous disincentives produce rampant under-reporting of worker poisonings, as EPA has recognized. EPA Opposition at 13, 21-22. Farmworkers often do not associate their symptoms with pesticide poisoning, they often lack health insurance or financial resources to seek medical attention, health care providers regularly misdiagnose organophosphate poisoning, and accurate diagnoses may not make their way into incident reporting databases. ER 1690 at slide 5; ER 1415 at 5; Response to Public Comments on PR Notice 2000-9, at 12 (Exhibit 2 to UFW Summary Judgment Motion) ("The Agency agrees that cases of pesticide poisoning incidents among the agricultural work force are likely to be significantly more numerous than those that are reported."). In light of this systemic



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under-reporting, EPA has used its standard risk assessment practices and scientifically sound data, not incident reports, to determine the thresholds for, and magnitude of, the risks posed by each pesticide use.

In contrast, for AZM, EPA relied on incident reports both to confirm and to downplay the worker risks of concern documented in EPA's risk assessments. As to the former use, EPA cited the anecdotal information provided in worker poisoning reports to confirm what its risk assessments showed – "that AZM does pose significant risk to workers" and that "there are risks of concern that merit more regulation." EPA Opposition at 20, 21. However, nowhere does EPA contend that confirmatory incident data is necessary to find that a pesticide poses a risk of concern. Surely if EPA found that a pesticide posed risks of concern using its standard methods, but there were no reported poisoning incidents, it could not, under FIFRA, allow the risks of concern without overriding benefits.

Nor is it appropriate to use the spotty incident reports to discount worker or environmental risks. Given its recognition that such reports provide no scientifically sound methodology for predicting the number of workers who will be harmed, EPA had no factual basis for its belief that "if severe adverse human health [effects] were occurring on a broad scale, these databases would reflect that fact." AR 1459 at 13. EPA also erroneously relied on a decline in reported poisonings from Poison Control Centers, AR 1459 at 6; AR 1357 at 29, when the sole source for this statistic cautioned that Poison Control Center data are "not the best source for occupational exposures." AR 1711 at 2. Since EPA appropriately takes the position that these sources of information cannot be used to quantify the frequency or magnitude of poisoning incidents, it is illogical for EPA to use the same data to discount serious risks documented through EPA's risk assessments.

The Washington medical monitoring data reveal the folly of EPA's approach. Under this program, workers are tested when they are exposed to organophosphates for more than a set number of hours and the results are compared to a baseline. This testing misses a substantial segment of worker exposures that persist for less than a month. Nonetheless, the results show that 10% and 20% had unsafe exposure levels during the first two years of the program. Given that EPA



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regulates to achieve 100 times the no effect level for these pesticides, these results are quite alarming. A substantial number of workers have experienced adverse effects in the form of depressed cholinesterase from pesticide exposure. Only three of the workers were exposed only to AZM, making AZM the definitive cause of those workers' effects, but AZM was one of the four pesticides used most frequently by workers who experienced cholinesterase inhibition. Registrants' Exhibit 8 at 46.[15] As EPA recognized in its response to comments, this association of AZM with cholinesterase inhibition should give cause for greater concern since it proves that EPA's risk assessment has predicted harm that is in fact occurring. AR 1689 at 2; AR 1702.[16]

EPA similarly erred in relying on the fact that it "is not aware of incident information, monitoring data, or other sources of information that suggest AZM is having immediate large-scale environmental impacts (such as a clear link to species population declines or extirpations)." AR 1459 at 13. Again, as with worker poisonings, no monitoring system exists that would produce such information, and the monitoring that does exist is sporadic and designed for other purposes.

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[15] The report submitted by the registrants indicates that Washington's Pesticide Incident Reporting and Tracking System, which is separate from the medical monitoring program, linked 10 poisoning incidents to AZM from 2000-2004. Registrants' Exhibit 8 at 39.

[16] The registrants argue that their biomonitoring study supports the notion that no severe human health incidents are occurring, quoting a portion of EPA's worker risk assessment observing that the study exposed workers for only one day. Registrants' Opposition at 20, quoting AR 1357 at 29. However, EPA elaborated in its response to comments, noting that workers would be exposed for consecutive days in real field conditions and that AZM exposures and effects peak after several days of exposure. AR 1689 at 2. As a result, EPA concluded that Bayer's biomonitoring study "cannot be reliably used to conclude that [cholinesterase inhibition] is not occurring in post-application workers as a result of AZM exposure." AR 1689 at 2.

The registrants also point to a decrease in the number of workers with unsafe cholinesterase inhibition between the first and second years of the Washington medical monitoring. An assessment of the program has attributed that decrease to a number of factors including a shift by the grower to organic farming, elimination of the use of organophosphates, and a reduction in the number of hours workers handle organophosphates to eliminate the need for testing. Registrants' Exhibit 8 at 31, 36 (AR 1920). A subsequent report elaborates on these changes. See also Final Report: Cholinesterase Monitoring of Pesticide Handlers 2004-2006 at 37 (2006), available at http://www.lni.wa.gov/Safety/Topics/AtoZ/Cholinesterase/files/2004-06ChESACreport.pdf. While this report is not in the administrative record, it explains a complex subject matter and explains that the decrease touted by the registrants appears to be due to reductions in exposure to AZM not to less severe consequences when AZM is used.



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For example, the U.S. Geological Survey has conducted spot-check monitoring of water bodies at times that have not been correlated with pesticide applications. Nonetheless, USGS detected AZM frequently in many water bodies and at levels that exceed aquatic life standards in some of them. AR 1459 at 4. Several water bodies have been listed as violating state water quality standards due to AZM contamination, even in the absence of comprehensive pesticide monitoring. AR 1459 at 4.[17] These detections provide real-world evidence that AZM is actually migrating into streams at levels associated with harm to fish, thereby confirming EPA's predictions of environmental harm in its risk assessment, as EPA has found. AR 1454 at 4, 6; AR 1356 at 11. In response to comments, EPA appropriately refused to draw conclusions from lack of a large number of ecological incidents in its database:

> This "trend" of decreasing adverse ecological incidents in the EIIS database is not unique to azinphos methyl and is likely a function of reduced reporting rather than a drastic decrease in pesticide risk to fish and wildlife. Further, since there is no nationwide, rigorous incident monitoring program in place, reported incidents can only be used as a line of evidence to support a risk conclusion that a given taxon may be at risk from a particular pesticide use. Given the haphazard nature of incident reporting, lack of incident data cannot suggest lack of ecological risk.

ER 1454 at 4. EPA acted contrary to this sound conclusion in relying on the lack of large-scale environmental incident reports in its 2006 AZM decision.

EPA's erroneous reliance on the lack of large-scale incident reports is made all the more unjustifiable because it failed to comply with the statutorily mandated process for it to determine whether AZM use would be likely to cause salmon population declines or extirpations. The Endangered Species Act ("ESA") requires EPA to ensure, through consultation, that its pesticide registrations will not jeopardize the survival and recovery of ESA-listed species. 16 U.S.C. § 1536(a)(2); Washington Toxics Coalition v. EPA, 413 F.3d 1024 (9th Cir. 2005). EPA has found that over two dozen listed salmon and steelhead may be adversely affected by re-registered AZM

[17] The registrants assert that the listing of impaired streams merely reveals presence of contaminants in water bodies above acceptable levels established in water quality standards. Registrants' Opposition at 23. While the development of precise cleanup plans admittedly comes later, the stream's listing indicates that AZM has been detected in streams at levels that violated state water quality standards.



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uses, yet it has failed to conduct the ESA-mandated consultation to ensure that AZM use will not cause jeopardy and to craft necessary mitigation. AR 1459 at 5. Moreover, it has not even conducted preliminary assessments to determine whether AZM is likely to adversely affect other listed species. While EPA asserts (at 23) that it took endangered species impacts into account in crafting mitigation for the phase-out period, it did so without complying with the ESA process designed to ensure that such mitigation will be adequate to protect listed species.[18]

As with worker poisonings, EPA insists that it cannot accurately quantify or predict the occurrence of fish kills and other environmental impacts in the absence of a comprehensive nationwide monitoring system. EPA Opposition at 24. Given this reality, EPA cannot credibly rely on the absence of large-scale reported environmental incidents to justify continuing the use of AZM.

G. EPA's Rejection of Organic Production as a Viable and Cost-Effective Alternative Runs Counter to the Available Evidence and Is Based on Speculation About Grower Desires Rather Than Objective Evidence.

In its motion for summary judgment, UFW showed that EPA rejected organic production as an alternative to AZM based on speculation, rather than evidence that organic production is infeasible or not cost-effective. While EPA compared AZM to other chemical pesticides, it believed a majority of growers would not want to shift to organic production and did not conduct the same type of analysis of the costs and feasibility of organic production for that reason.

In rejecting organic production as a viable alternative, EPA asked whether a majority of growers would choose to shift to organic production. This approach runs counter to EPA's stated inquiry in conducting benefits assessments. In its AZM grower impact assessments, EPA explains that the benefits of a pesticide are to be measured as revenue losses and cost increases to pesticide

[18] The registrants try (at 21) to downplay Washington Toxics Coalition by calling it "purely procedural." While this Court ordered EPA to comply with ESA procedures in that case, Congress devised those procedures to ensure that federal agencies would comply with the ESA's substantive mandate to avoid taking actions, like pesticide registrations, that may wipe out endangered species. See Thomas v. Peterson, 753 F.2d 754 (9th Cir. 1985). Had EPA complied with its ESA duties, the consultations might have determined that an immediate ban of AZM uses is necessary to protect salmon.



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users if the pesticide were not available, and it describes its approach as designed to identify the least costly options available to users in light of the use restrictions. AR 1253 at 18; AR 1249 at 8; AR 1246 at 11; AR 1251 at 8; AR 1244 at 20.

When it came to considering organic production, however, EPA deviated from this stated analysis and made two errors. First, it focused on the desires of a majority of growers and refused to run the numbers to determine whether organic production would be cost-effective. See, e.g., AR 1253 at 19-21. As EPA explains, its benefits assessments compare "current production practices and costs with the most likely (i.e. cost-effective) pest control options that the majority of growers would turn to in the absence of the pesticide." EPA Opposition at 13-14.

By focusing on the preferences of a majority of growers rather than the cost-effective alternatives, EPA asked the wrong question. UFW is submitting the Second Declaration of Dr. Frank Ackerman (Oct. 2, 2007), an economics expert, who explains that the feasibility and cost-effectiveness of alternatives are objective issues that depend on hard data, not the preferences of the regulated entity.[19] Rather than conduct an objective inquiry into the feasibility, efficacy, and cost-effectiveness of alternatives, EPA embarked on a subjective prediction of grower choices and behaviors. Rarely will a regulated entity choose to make changes in its production methods to avoid harm to workers or the environment, but such a desire to avoid change does not make the production method infeasible or unduly costly. By way of analogy, the Occupational Safety and Health Administration establishes workplace standards not based on the subjective desires of the employers, but rather based on whether the safeguard is objectively feasible or "capable of being done." American Textile Mfrs Institute v. Donovan, 452 U.S. 490, 508-09, 530-36 (1981); see, e.g., Forging Industry Ass'n v. Secretary of Labor, 773 F.2d 1436, 1452-54 (4th Cir. 1985); United

[19] This declaration is admissible as extra-record evidence to identify the relevant factors EPA should have, but did not, consider, and to explain the standard nature of a feasibility or cost-effectiveness inquiry in the regulatory arena and how EPA deviated from that approach. See Center for Biological Diversity v. Fish and Wildlife Serv., 450 F.3d 930, 943 (9th Cir. 2006) (extra-record evidence is admissible when relevant to whether agency has considered all the relevant factors).



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Steelworkers of America v. Marshall, 647 F.2d 1189, 1265-66, 1272 (D.C. Cir. 1981); American Iron & Steel Institute v. OSHA, 577 F.2d 825, 834-36 (3d Cir. 1978). Similarly, federal agencies have been directed to conduct objective analyses of economic costs of regulatory changes based on data and studies with sufficient detail to permit independent assessment and verification of the results. Office of Management and Budget Guidance on Economic Analysis of Federal Regulations under Executive Order 12,866, at 31 (Jan. 11, 1996) (AR 1341). EPA cannot rely on the subjective preferences of pesticide users, detached from any rational economic feasibility assessment, to limit its consideration of alternatives to AZM.

Second, EPA dismissed organic production as a viable option based on an erroneous belief that the premium price commanded by organic produce is likely to decline. This belief runs counter to the available evidence in the record, and articles by the same government researchers and from the same government website that EPA used find exactly the opposite. See UFW Motion at 33; Second Ackerman Declaration ¶¶ 6-7.[20] Since EPA erroneously believed organic prices would decline, it is not surprising that it also believed organic producers would fail to recoup their investment. Thus, EPA stated its belief that growers would not want to change to organic production because they would need to use different marketing channels, and that organic production would not be viable because it takes three years to become certified as organic. Id. at 33-34. Given its disregard of the substantial price premium for organic crops that all the experts believe will persist into the future, EPA never did the math to see whether the returns would make the transition worthwhile.

In its opposition (at 27), EPA points to its discussion of organic production. The deficiency is not the absence of any discussion, but that EPA reached conclusions that run counter to the

[20] UFW has cited to other documents by the same authors of the principal article cited by EPA for its disregard of premium organic prices, as well as other articles and datasets from the U.S. Department of Agriculture website cited by EPA. A cursory review of materials on that website reveals that EPA conducted an insufficient investigation of the viability of organic production. This evidence is admissible for this purpose. See Love, 858 F.2d at 1356-60; West Harlem Environmental Action, 380 F. Supp. 2d at 295 n.2.



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readily available evidence. EPA must conduct a thorough investigation of the viability of alternatives. See Love, 858 F.2d at 1358-62. It cannot rely on cursory, incomplete, or scanty data, but instead must have sufficient evidence to investigate various alternatives and determine their relative costs and efficacy. Id.; West Harlem Environmental Action, 380 F. Supp. 2d at 294-96. EPA did not even conduct the analysis necessary to ascertain whether organic production may be the most cost-effective alternative to AZM based on its unsupported supposition that the price premium will soon dissipate. Moreover, in its view, even if such an inquiry would have found organic production to be the most cost-effective alternative, it would be justified in rejecting this option because most growers would prefer not to make that type of change. EPA fell far short by refusing to analyze the cost-effectiveness of organic alternatives to AZM based on its unsupported belief that organic prices would soon decline and that a majority of growers would not want to shift to organic production, even if it were profitable to do so.

## III. EPA FAILED TO CONDUCT A RISK-BENEFIT ANALYSIS THAT OBJECTIVELY WEIGHED AZM'S BENEFITS AGAINST THE SEVERITY AND MAGNITUDE OF THE RISKS TO WORKERS, BYSTANDERS, AND THE ENVIRONMENT.

EPA acknowledges that a pesticide use that poses risks of concern is ineligible for registration unless its benefits outweigh those risks. EPA Opposition at 3-4. EPA found that workers who apply AZM in open cabs face risks of concern, as do workers who apply AZM aerially to blueberries. Farmworkers who enter fields after AZM spraying to pick apples, pears, cherries, blueberries, and parsley similarly face risks of concern. AZM also poses risks of concern to fish, mammals, birds, and beneficial insects, such as honey bees, and it is likely to adversely affect more than two dozen threatened or endangered salmon and steelhead populations. EPA documented each of these risks of concerns in its risk assessments and also found that actual monitoring, spotty though it may be, confirmed that real-world environmental exposures to AZM are occurring at levels that may cause the feared adverse effects. These risks persist even after the mitigation required in both the 2001 IRED and in its 2006 AZM decision. Because these AZM uses pose risks of concern, they are ineligible for continued registration unless the registrant proves and EPA finds



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benefits that outweigh the risks.

For the numerous reasons described above, EPA lacked an objective demonstrable basis for its conclusory claim that such overriding benefits exist and therefore it failed to take into account the full social, environmental, and economic costs and benefits of continued AZM use. While EPA announced that the costs to growers necessitated a six-year transition period, it never compared those costs to the magnitude of the risks that would occur during that six-year period. Instead, EPA sought to minimize the worker and environmental risks based on sparse incident reporting that cannot credibly be used for this purpose, and by asserting that some additional mitigation would be employed during the phase-out. These deficiencies are described in Section II above, which provides the basis for UFW's argument that EPA has failed to conduct the type of comprehensive and objective risk-benefit balancing required under FIFRA. EPA offers two reasons for failing to conduct such a risk-benefit analysis, but neither has merit.

First, EPA justifies failing to integrate the risks into its decision over the length of the phase-out by feigning an inability to quantify the economic impact of the health and environmental harm from AZM. EPA is correct that the spotty monitoring and incident reporting do not allow EPA to quantify the magnitude of worker poisonings or environmental contamination from AZM, but the fact that EPA may not be able to monetize the worker and environmental risks does not allow EPA to give insufficient weight to those risks.[21]

Second, EPA sets up a straw man by arguing that UFW seeks a rigid, quantitative cost-benefit assessment. UFW agrees that FIFRA erects no such mandate. In its motion, UFW described EPA's prior interpretation of FIFRA as requiring a quantitative comparison of costs and benefits, as well as its more objective and partial quantification of worker risks in its regulatory impact analysis of the worker protection standard to illustrate generally the type of objective

[21] EPA asserts (at 24) that UFW has not explained how EPA could quantify environmental risks. In making this claim, EPA ignores the declaration and comments submitted by Dr. Frank Ackerman, which describe how agencies have quantified and even monetized harm to people, as well as to species, and in particular to salmon and endangered species, in cost-benefit analyses. AR 1340, 1415.



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analysis required under FIFRA. UFW Motion at 29-30. UFW faulted EPA for failing to aggregate the various types of harm that each AZM use causes and for monetizing and elevating one impact – the costs to growers – above the serious risks to workers and the environment. Id. at 30. While EPA did not need to ascribe dollar amounts to worker poisonings, water contamination, fish kills, and the like, it had to give full weight to each of these risks of concern and it had to have an objective and demonstrable basis for finding that benefits outweighed each of these risks separately and all of them together.

For their part, the registrants assert that EPA was justified in not addressing the risks to farmworker children from AZM drift because it had dealt with related issues in other proceedings dealing with different pesticides under a different statutory scheme – the Food Quality Protection Act ("FQPA"). Registrants Opposition at 17-19. As a preliminary matter, this is a post hoc rationalization offered by the registrants to fill a gap in EPA's decision. While EPA may be entitled to rely on its analysis in one proceeding in a subsequent one, it did not do so here. For that reason, EPA has opposed the registrants' motion to add the two independent decisions to the administrative record in this case.[22]

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[22] The registrants also argue that the risks of AZM should be discounted based on a discredited and rejected study that Bayer conducted using 8 male human subjects. The registrants fail to tell the Court the full context in which the human study was found wanting. In 2005, Congress prohibited EPA from using human studies until EPA promulgated regulations that would ensure that such studies comported with ethical and scientific standards. Department of the Interior, Environment, and Related Agencies Appropriations Act, 2006, § 201, Pub. L. 109-54, 119 Stat. 499, 532 (Aug. 2, 2005). In 2006, EPA adopted regulations to establish standards governing EPA's use of human studies to reduce public health protection from pesticides. 71 Fed. Reg. 6138 (Feb. 2, 2006). The regulations established the Human Studies Review Board ("HSRB") to subject human testing to independent review to ensure compliance with ethical and scientific principles. See http://www.epa.gov.osainter/hsrb/about.ntm. The registrants offer a critical view of the HSRB meeting that addressed AZM, but overlook the written report adopted by the full HSRB finding that Bayer's human test should not be used in EPA's risk assessment because it used only a single dose contrary to the scientific standards adopted by a National Academy of Sciences report. April 4-6, 2006 Meeting HSRB Report at 3, 11-12, 33-36 (June 26, 2006) (available at http://www.epa.gov/osainter/hsrb/files/meeting-materials/apr-4-6-2006-public-meeting/april2006mtgfinalreport62606.pdf). The study also failed to meet the specific ethical standards prevalent at the time the research was conducted. Id. at 37. As part of its agreement to a voluntary cancellation, Bayer insisted on another EPA review of the human study. In this post-



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Nor could EPA properly have relied on the two FQPA decisions here. In those proceedings, EPA decided that the evidence was too inconclusive to deem farm children to be a major identifiable subpopulation with greater sensitivities and vulnerabilities to pesticides than other children and subpopulations. Such a designation would have required targeted exposure analyses and extra precautions for this population in setting tolerances for the amount of pesticide residues that could be on food. 69 Fed. Reg. 30,042, 30,050, 30,054 (May 26, 2004); 70 Fed. Reg. 46,706, 46,716, 46,725 (Aug. 10, 2005). This determination did not excuse EPA from taking children's exposures and vulnerabilities into account in FIFRA decisions regulating the use of that pesticide. Indeed, in those decisions, EPA assessed the extent to which the pesticides at issue would drift into homes and schools. 69 Fed. Reg. at 30,054-55; 70 Fed. Reg. at 46,717-18. Here, AZM drift exposes children and other bystanders to risks of concern, AR 1456, and specific studies revealed AZM residues in the children of farmworkers. AR 1705; 1921, 1922. EPA reviewed AZM studies showing neurobehavioral effects in fetuses and lactating infants, as well as evidence of exposures to AZM brought home on workers' clothing and skin. AR 1689 at 3-4. EPA did not dispute this evidence, but asserted that its assessments used a more sensitive endpoint. Id. In the end, EPA crafted mitigation measures in the form of buffer zones to reduce bystander exposures to AZM in homes, schools, day care centers, and other occupied dwellings. AR 1689 at 4; AR 1459 at 15, 18, 20, 24, 26. However, the sole assessment of the magnitude of bystander risks came at the eleventh hour when EPA estimated the MOEs for various size buffers, the smallest of which was 60-feet. AR 1456. For several AZM uses, a 60-foot buffer will leave children and other bystanders exposed to drift that poses greater risks than EPA's safety levels, particularly early in the season. AR 1456. EPA never addressed these risks in asserting that AZM's benefits outweigh its risks.

While EPA failed to account explicitly for risks to children and other bystanders in its risk

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decisional review, an internal EPA meeting found that the 100-fold safety factor for AZM is supported by evidence and necessary to protect people in accordance with EPA's risk assessment policies. Registrants' Exhibit 3. Moreover, the HSRB has conducted no additional review of Bayer's study so its previous condemnation of that study still stands.



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assessments or risk-benefit analysis, EPA documented risks of concern to workers and the environment using its risk assessments. In determining whether benefits outweigh these risks, EPA must conduct an objective analysis that aggregates the harm from worker poisonings, children's exposures, water contamination, fish kills, honey bee mortalities, and other adverse effects from AZM use. 7 U.S.C. § 136(bb) (requiring EPA to take into account "the economic, social, and environmental costs and benefits of the use of any pesticide"). EPA does not dispute this obligation, but asserts that it conducted a comprehensive risk-benefit analysis. As discussed in Section II above, however, EPA conducted inadequate investigations of the viability of AZM alternatives and mitigation. Had EPA required demonstrable overriding benefits, it would have developed a far different risk-benefit picture, one that would not have allowed six more years of AZM usage and the resulting harm. The Court should remand the 2006 AZM decision for reconsideration based on a full risk-benefit analysis that accounts fully for and balances all risks and benefits in an objective manner.

## IV. THIS COURT HAS JURISDICTION.

### A. FIFRA Provides for District Court Review of Final Registration Decisions.

In asserting that this Court lacks jurisdiction, the registrants ignore FIFRA's system of judicial review which provides for court of appeals review only where EPA has issued an order after a quasi-judicial administrative hearing before the agency. See 7 U.S.C. § 136n(b) (establishing exclusive court of appeals jurisdiction to review "the validity of any order issued by the Administrator following a public hearing."). The defining feature of appellate review under § 136n(b) is EPA's issuance of an order following a public hearing in an administrative quasi-judicial proceeding. Environmental Defense Fund v. Costle, 631 F.2d 922, 926-32 (D.C. Cir. 1980).

In contrast, the district courts have jurisdiction to hear challenges to certain specified and other final actions undertaken by EPA under FIFRA without a quasi-judicial proceeding before the agency. Thus, 7 U.S.C. § 136n(a) provides: "Except as otherwise provided in" section 136n, district



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courts have the authority under subsection 136n(a) to review "the refusal of [EPA] to cancel or suspend a registration or to change the classification not following a hearing and other final actions of the Administrator."

FIFRA's legislative history confirms Congress's intent to bifurcate judicial review in this manner. The Senate Agriculture and Forestry Committee explained: "In short, the Committee . . . believes that matters which have not been heard before should go to courts of original jurisdiction and appeals from cases which have already been administratively heard and decided should go to appellate courts. The question is really that simple." S. Rep. No. 92-838, reprinted in 1972 USCCAN at 4070. The Senate Committee elaborated:

> After a hearing [,] judicial review on petition by any person adversely affected is properly lodged in courts of appeals, since an adequate record exists for such review. Where, however, the Administrator has determined no substantial question of safety exists which warrants formal review, and thus has refused to hold a hearing, review should be by district court since there is no record for the court of appeals.

Id. at 4004.

In denying EPA's motion to dismiss at the outset of this case, this Court held that EPA's reregistration decisions for AZM and phosmet are "final agency actions" reviewable under 7 U.S.C. § 136n(a), and that reviewing these determinations "for conformity to the standards set forth in FIFRA . . . is an appropriate exercise of the Court's power of judicial review. 7 U.S.C. § 136n(a)." Order Denying Motion to Dismiss at 14 (Feb. 14, 2005). Moreover, while EPA had initially argued that UFW had to exhaust administrative remedies, EPA abandoned this argument at the hearing on the motion to dismiss in light of FIFRA's clear grant of district court jurisdiction to review refusals to cancel and other final EPA actions without first obtaining further EPA review. Id. at 13.

Without addressing this Court's prior ruling, the registrants contend that 7 U.S.C. § 136n(a) (also called FIFRA § 16(a)) is inapplicable, and that another FIFRA judicial review provision controls. That provision, subsection (m) of § 4, provides that "[a]ny failure of the Administrator to take any action required by this section shall be subject to judicial review under the procedures prescribed by section 136n(b) of this title." FIFRA § 4(m), 7 U.S.C. § 136a-1(m). Subsection 4(m)



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pertains solely to failures to undertake actions required under the reregistration procedures set out in section 4, which establish deadlines for the five-phase process that produces reregistration decisions. It does not extend to challenges to the outcome of that process, such as a final registration decision or a refusal to cancel a registration, for violating, inter alia, FIFRA's risk-benefit standard set out in FIFRA § 3, 7 U.S.C. § 136a(c)(5). See West Harlem Environmental Action, 380 F. Supp. 2d at 289 (district court had jurisdiction over amendment to FIFRA registration); American Farm Bureau v. EPA, 121 F. Supp. 2d 84, 106 (D.D.C. 2000) (district court had jurisdiction over challenge to cancellation order).[23]

B. Plaintiffs Have Standing.

The registrants accuse plaintiffs of presenting only "undifferentiated concerns" about the effects of AZM. They can make this accusation only by ignoring the Declaration of Arnulfo Lopez, who explains that he has supported himself and his family since 1982 by working in the fields and orchards of California, Oregon, and Idaho, and that "I have worked in and around fields that I believe were treated with azinphos-methyl." While these allegations are sufficient, plaintiffs are submitting additional declarations from members of plaintiff organizations who will be adversely affected by the continued use of AZM over the next six years. For example, Rogelio Alvarez, a UFW member, works in potato fields just 20-feet away from apple orchards where AZM and other organophosphate pesticides are sprayed. See Declaration of Rogelio Alvarez (Oct. 2007).[24] It is well-settled that the Court need find only that one plaintiff has standing to decide a case. See Massachusetts v. EPA, 127 S. Ct. 1438, 1453 (2007); Bowsher v. Synar, 478 U.S. 714, 721 (1986).

CONCLUSION

The Court should declare that EPA acted unlawfully in allowing continued use of AZM for the next six years and order EPA to make a new AZM registration decision within 90 days.

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[23] Natural Resources Defense Council v. Johnson, 461 F.3d 164 (2d Cir. 2006), construed the FQPA, which established exclusive court of appeals' jurisdiction over that challenge.

[24] Mr. Alvarez has approved his declaration. UFW will file the signed declaration, along with another declaration that has been delayed due to the harvest season.



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Respectfully submitted this 4th day of October, 2007.

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CERTIFICATE OF SERVICE

I am a citizen of the United States and a resident of the State of Washington. I am over 18 years of age and not a party to this action. My business address is 705 Second Avenue, Suite 203, Seattle, Washington 98104.

On October 4, 2007, I served a true and correct copy of:

1. Opposition to Cross-Motions for Summary Judgment and Reply in Support of Plaintiffs' Motion for Partial Summary Judgment as to Azinphos-Methyl;
2. Second Declaration of Frank Ackerman; and
3. Declaration of Rogelio Alvarez.

on the following parties:

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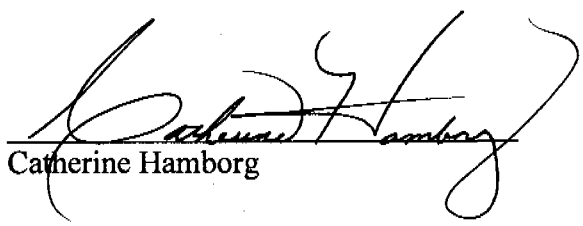
I, Catherine Hamborg, declare under penalty of perjury that the foregoing is true and correct. Executed on this 4th day of October, 2007, at Seattle, Washington.



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